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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LIEU, JULIE BICHNGOC

ART UNIT	PAPER NUMBER
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2636

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,294

Applicant(s)

STRODA ET AL.

Examiner

Julie Lieu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-20, 22, 24, 25, 27, 29 and 31 is/are allowed.
- 6) ☒ Claim(s) 7-16, 21, 23, 26, 28, 30, and 32-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to amendment filed August 30, 04. Claims 7-9, 11, 17, 21, 23, and 27 have been amended. Claim 16 has been canceled. New claims 32-44 have been added.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boon (US Patent No. 5,796,059).

Claim 11:

Boon discloses a system for monitoring a patient, comprising:

- a. A pressure pad for providing a signal indicating a pressure condition;
- b. A control unit connected to the pressure pad and responsive to the signal; and
- c. A casing 52 at least partly encasing the controller unit and the pressure pad.

Claim 12:

The pressure pad in Boon is activated by removal of pressure and inactivated by application of pressure.

Claim 32:

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Boon discloses an alarm means activated by said signal indicating a pressure condition.

Claim 36:

Boon discloses a system for monitoring a patient, comprising:

- a. A pressure sensor for providing a signal indicating a pressure condition;
- b. An alarm means (fig. 3) connected to the pressure sensor and responsive to the signal; and
- c. A casing 52 at least partly encasing the controller unit and the pressure pad.

4. Claims 7-10 are rejected under 35 U. S. C. 132(a) as being unpatentable over Cross (US Patent No. 5,494,046) in view of Boon (US Patent No. 5,796,059).

Claim 7:

Cross discloses a method of monitoring a patient, comprising the steps of attaching a fastener (fig. 4) to the patient, wherein if the patient moves beyond a predetermined distance, a switch moves between one of an open state of a closed state to the other of the open and closed state. Cross fails to disclose placing pressure pad under the patient that activates a switch when energize. However, such concept is old and well known in the art as taught in Boon. Therefore, it would have been obvious to one skilled in the art to combine the system taught in Boon into the system in Cross because it would further enhance the detection of the system. Cross provides an alarm signal when the first switch is activated, that is when a patient is moved beyond a predetermined distance. It would also have been obvious to one skilled in the art provide an alarm signal when the pressure on the pressure pad is removed.

The reference fails to disclose disposing the first pressure pad and replacing with the second pressure pad. However, it would have been obvious to one skilled in the art to make the pressure pad in the combined system of Cross and Boon disposable as desired and replacing the disposable pad with a new one for use by another patient for sanitary reasons. This claimed feature only presents an obvious choice, not an inventive step because the function of the device would not thereby be modified.

Claim 8:

The fastener is attached to the clothing of the patient in Cross. See fig. 4.

Claim 9:

Cross teaches the step of providing a verbal message to the patient.

Claim 10:

Cross also teaches the step of transmitting a signal to a remote station and providing an alarm to a caretaker at the remote station.

Claim Rejections - 35 USC § 103

5. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent No. 5,494,046)

Claim 13:

Boon fails to disclose a recorded voice message sounding within hearing distance of the patient. Nonetheless, such feature is conventional in the art as taught in Cross wherein the voice alarm is located near the station. In light of this teaching it would have been obvious to one

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skilled in the art to provide a verbal warning device within the hearing distance of the system in Boon for the same purpose as in Cross.

Claim 14:

In Boon, the pressure pad responds to pressure by reducing electrical resistance between a first point and a second point. The apparatus including a switch armed upon the reduction of electrical resistance and an alarm for providing the alarm when the switch has been armed and the electrical resistance is under a predetermined resistance threshold, wherein a movement of the patient from the pressure pad triggers the alarm. Col. 3, third paragraph to col. 4, first paragraph. A time delay, such as 1 second, is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art, as taught in Cross. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

Claim 15:

The alarm in Boon provides the alarm when the switch has been armed and electrical resistance is under the predetermined resistance threshold. Regarding the time delay between 2 seconds and 3 seconds in duration, it is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art as taught in Cross. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

6. Claims 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059).

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Claim 33:

Boon does not show a battery within the casing. However, it would have been obvious to power the device with battery and include it within the casing as desired because the use of battery as an alternative power supply in place of household power supply is conventional in the art and safe to use.

Claim 34:

At least one of the pressure pad and battery in Boon are at least adjacent to the alarm means in Boon.

Claim 35:

The casing in Boon is flexible. It is not clearly stated that it is waterproof. However, it would have been obvious to one skilled in the art to use waterproof casing for the device in Boon because it would protect the device from external conditions.

Claims 37-39:

The rejection of claims 37-39 recites the rejection of claims 33-35.

Claim 40:

Boon discloses a system for monitoring a patient, comprising:

- a. A pressure sensor for providing a signal indicating a pressure condition;
- b. An alarm means (fig. 3) connected to the pressure sensor and responsive to the signal; and
- c. A casing 52 at least partly encasing and sealed around the pressure sensor.

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The control unit in Boon is outside of the casing. However, it would have been obvious to include the control unit within the casing in Boon as desired because the shift of the location of the part would not thereby modify the function of the device.

Claim 41:

Boon does not show a battery within the casing. However, it would have been obvious to power the device with battery and include it within the casing as desired because the use of battery as an alternative power supply in place of household power supply is conventional in the art and safe to use.

Claims 42-44:

The rejection of claims 42-44 recites the rejection of claims 33-35.

7. Claims 21, 23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent No. 5,494,046) and Triplett et al. (US Patent No. 4,175,263).

Claim 21 and 23:

Boon discloses a method of monitoring a patient, comprising the steps of:

- a. Placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;
- b. Energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);

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- c. Applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)
- d. Arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;
- e. Activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad
- f. Disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays, such as that in Cross, because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off. Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

The reference fails to disclose disposing the first pressure pad and replacing with the second pressure pad. However, it would have been obvious to one skilled in the art to make the pressure pad in the combined system of Cross and Boon disposable as desired and replacing the disposable pad with a new one for use by another patient for sanitary reasons. This claimed feature only presents an obvious choice, not an inventive step because the function of the device would not thereby be modified.

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position. The second sensor used in Triplett is a mechanical switch.

Claim 26:

Boon fails to disclose a second sensor. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in

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Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position. The second sensor used in Triplett is a mechanical switch (see US 3,781,843, as indicated in Triplett, of which reference is provided herein).

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Triplett et al. (US Patent No. 4,175,263).

Claim 28:

Boon discloses a system for monitoring a patient, comprising:

- a. A pressure pad providing a signal indicating a pressure condition;
- b. A control housing connected to and located adjacent to the pressure pad and responsive to the signal ;
- c. A casing at least partly encasing the control housing and the pressure pad.

Boon fails to disclose a second sensor. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed (direction of motion or the patient), as indicated by the second sensor, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position.

Allowable Subject Matter

9. Claims 17-20, 22, 24-25, 27, 29 and 31 are allowed.

Applicant's Remarks

10. Applicant's arguments filed 8/30/04 have been fully considered but they are not persuasive.

Argument 1:

“Neither Cross nor Triplett et al. contain a suggestion of a casing enclosing or being sealed around an alarm, control unit or control housing, how it could be done, nor the advantage gained or problem solved by it and thus can not cure the problem with the rejection over Boon even if expanded to be a 103 rejection that takes into account the other references. Claim 12 depends from claim 11 and avoids a rejection under 35 U.S.C. 102(b) for the same reason. For a claim to be anticipated under 35 U.S.C. 102(b), the reference must show every feature recited in the claim. That is not the case here.”

Argument 2:

“Claim 7 is directed to a method of using a disposable pad and a pull type fall monitoring safety device to detect patients that only slump over rather than leaving a location and patients

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who remove the pull type alarm. Neither Cross nor Boon teaches the problems solved by this combination nor the claimed solution. Moreover, claim 7 is also directed to a technique that permits replacement of the pad when patients are changed for sanitation purposes but permits keeping of the rest of the apparatus. The mere fact that some of the components of this device are in the prior art is not sufficient to form a prima facie case of unpatentability. Instead the Examiner must find a suggestion of the combination of pads in the prior art to arrive at the invention, which has not been done in this case.”

Applicant's Remarks

Argument 1:

The claim recites “at least partly encasing” which is the case in Boon. Therefore, the applicant’s argument is not deemed persuasive.

Argument 2:

In response to applicant's argument that there is no suggestion for changing the pad when patients are changed for sanitation purposes, the examiner recognizes that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. However, it must be recognized that any judgment on obviousness is in a sense not necessary based on

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actual suggestion and there is no requirement that a motivation or modification be expressly articulated.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

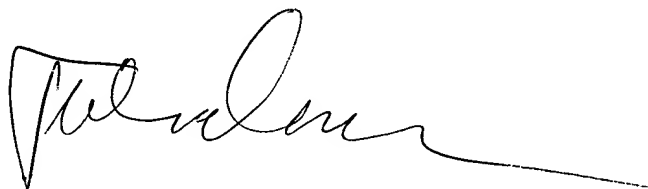
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Lieu whose telephone number is 571-272-2978. The examiner can normally be reached on Mon-Fri 9AM-6PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Hofsass can be reached on 571-272-2981. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Julie Lieu', with a long horizontal flourish extending to the right.

Julie Lieu
Primary Examiner
Art Unit 2636

May 25, 04